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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/585,546
Filing Date: March 02, 2009
Appellant(s): KROTKIEWSKI, MARCIN

Eugene C. Rzucidlo
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed September 12, 2011 appealing from the Office action mailed March 14, 2011.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1-3, 5-8 and 17.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. Rejection of claims 1-3, 5-8 and 17 under 35 U.S.C. 112, second paragraph.

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

Liao et al. Biochem. Biophys. Res. Commun. (1995), vol. 214, pp. 833-838.

Botancial.com; www.botanical.com/botanical/mgmh/b/bircom43.html; accessed 6-2010.

US 6,610,749	LIAO	8-2003
US 5,804,596	MAJEED	9-1998
US 7,279,184	GOW	10-2007
US 6,251,888	DE LA HARPE	6-2001
US 2003/0059403	CHOKSHI	3-2003
BE 1009545	SCHOPION	5-1997

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1, 3, 5-8 and 17 stand finally rejected under 35 U.S.C. 103(a) as being unpatentable over Liao (US 6,610,749), Majeed (US 5,804,596), Gow (US 7,279,184), de la Harpe (US 6,251,888), and BE 1009545.

Liao teaches using isolated EGCG, a catechin, extracted from green tea to reduce body weight. Isolated EGCG as taught by the reference is a green tea extract that is 100% EGCG; thus, the green tea extract meets the limitations of the appellant's claims which require more than 70% by weight of catechins in the green tea extract. The composition contains ingredients such as cellulose and magnesium stearate. The EGCG is extracted using the method taught in Liao et al. (Biochem. Biophys. Res. Commun. (1995), vol. 214, pp. 833-838) which extracts the green tea using water and ethyl acetate (see "Materials", p. 834 of Liao et al. and columns 12 and 14 of the patent document).

Majeed teaches using a composition comprising 1 to 40% forskohlin extracted from Coleus forskohlii to promote lean body mass. The C. forskohlii extract can contain from about 15% to 100% forskohlin (see column 6, lines 16-27). Forskohlin is a type of diterpene (as defined by the appellant at paragraph 8 of the present specification). Thus, Majeed is considered to teach a C. forskohlii extract with at least 10% by weight of diterpene forskohlin.

Gow teaches using Ilex paraguariensis (yerba mate) extract to induce weight loss (see first full paragraph of column 23). The extract can contain 0.8% caffeine and 2.8% chlorogenic acid (3-Caffeoylquinic acid) (see Table 2, SFE CO2 extract). This amount of caffeine and caffeoylquinic acid meets the limitations of the appellant's claims.

De la Harpe teaches using Betula pubescens to increase lean body mass and reduce body fat (see claims 42 and 43). The composition also contains ingredients such as microcrystalline cellulose and magnesium stearate (see column 6, lines 2 and 23). B. pubescens is synonymous with B. alba (see www.botanical.com/botanical/mgmh/b/bircom43.html). The reference does not teach that the B. pubescens contains at most 3% flavonoids. However, BE '545 teaches using birch leaves to provide a slimming effect (see English translation). Thus, an artisan of ordinary skill would reasonably expect that birch leaves would be useful in the composition taught by de la Harpe. This reasonable expectation of success would motivate the artisan to modify de la Harpe to include the use of birch leaves. The appellant's specification states that birch leaves contain 2-3% flavonoids (see paragraph 0009). Thus, the birch as suggested by de la Harpe and BE '545 meet the limitations of claim 1.

These references show that it was well known in the art at the time of the invention to use the claimed ingredients in compositions that would treat obesity. It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art.

Based on the disclosure by these references that these substances are used in compositions that would treat obesity, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating compositions to treat obesity. Therefore, the artisan would have been motivated to combine the claimed ingredients into a single composition. No patentable invention resides in combining old

ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See MPEP section 2144.06, In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980), Ex parte Quadranti, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992).

The references do not specifically teach adding the ingredients in the amounts claimed by the appellant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The references teach that each of the claimed ingredients is a pharmaceutically active ingredient. An artisan of ordinary skill would routinely modify the amount of pharmaceutically active ingredients based on the patient's age, weight, gender, and condition. Therefore, an artisan would have been motivated to modify the amount of each ingredient in the combination in order to formulate a product that best achieves the desired results set forth in the references. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of the appellant's invention.

Claim 2 stands finally rejected under 35 U.S.C. 103(a) as being unpatentable over Liao (US 6,610,749), Majeed (US 5,804,596), Gow (US 7,279,184), de la Harpe (US 6,251,888), and BE 1009545 as applied to claims 1, 3, 5-8 and 17 above, and further in view of Chokshi (US 2003/0059403).

The teachings of Liao, Majeed, Gow, de la Harpe, and BE '545 are discussed above. The references do not specifically teach using white kidney bean extract in the composition. Chokshi teaches using white kidney bean extract to induce weight loss (see paragraphs 45, 82 and claims). These references show that it was well known in the art at the time of the invention to use the claimed ingredients in compositions that would treat obesity. It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art.

Based on the disclosure by these references that these substances are used in compositions that would treat obesity, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating compositions to treat obesity. Therefore, the artisan would have been motivated to combine the claimed ingredients into a single composition. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See MPEP section 2144.06, In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980), Ex parte Quadranti, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992).

(10) Response to Argument

Regarding the 103(a) rejections of record, the appellant argues that Majeed does not teach a C. forskohlii extract which contains at least 10% by weight of diterpene forskolin as required

by claim 1. However, as discussed above, this reference teaches that use of a C. forskohlii extract which contains forskolin. The C. forskohlii extract can contain from about 15% to 100% forskolin (see column 6, lines16-27). Forskolin is a type of diterpene. The appellant's specification describes Majeed as containing a C. forskohlii extract with diterpene forskolin (see paragraph [0008]). Thus, Majeed is considered to teach a C. forskohlii extract with at least 10% by weight of diterpene forskolin because the reference teaches that the extract can contain 15% to 100% of this diterpene.

The appellant also argues that the claimed invention is patentable over the prior art because Figures 2A, 2B and 3 show that the composition produces synergistic results. The appellant argues that Figure 2A shows that each individual ingredient results in an increase in body weight from 42 to 46% while the results for the combined ingredients show an increase of 32%. The appellant also argues that Figure 2B shows that each individual ingredient results in a 71 to 79% change in body weight while the results for the combined ingredients show a change of 60%. The appellant states that Figure 3 shows that the mean food intake is significantly lower with the combined ingredients in comparison with the individual ingredients. The appellant states that these results show that the claimed composition produces synergistic results.

However, the results shown are not considered to show synergistic results. The results shown in Figures 2A, 2B and C compare dosages of the active ingredients that are set forth in Table 2 on page 10 of the specification. Table 2 shows administration of 6.95 mg of the formulation of the invention. The formulation of the invention is described in Table 1 as containing green tea extract, C. forskholii extract, yerba mate extract and B. alba extract. Table 2 shows administration of 0.17 mg of C. forskholii, 0.5 mg of B. alba, 0.5 mg of yerba mate, and

5.33 mg of EGCG for comparison with the inventive formula. As can be seen in Table 2, the administered dosage of the formulation of the invention was 40 times greater than the administered dosage of C. forskholii, 14 times greater than the administered dosage of B. alba and yerba mate, and 1.5 greater more than the administered dosage of EGCG. Clearly the administered dosage of the inventive formula is significantly greater than the comparative dosages. It is not considered to be unexpected that a higher dosage of active ingredients would produce a greater effect. In addition, it is not unexpected that a higher dosage of a combination of four known weight loss ingredients would function in an increased manner in comparison with a lesser dosage of one ingredient.

In addition, the appellant argues that the results shown in Figures 2A and 2B are commensurate in scope with the claimed invention. The appellant argues that an artisan would have expected similar results for all of the possible ranges of the individual components. However, the appellant has provided no reasoning or evidence to support this assertion. The appellant's claims are drawn to a broad range for each ingredient. The data shown in the specification show one amount for each ingredient. MPEP section 716.02(d) requires that any showing of unexpected results must be reviewed to see if the results occur over the entire claimed range. MPEP section 716.02(d)I states "...The nonobviousness of a broader claimed range can be supported by evidence based on unexpected results from testing a narrower range if one of ordinary skill in the art would be able to determine a **trend** in the exemplified data which would allow the artisan to reasonably extend the probative value thereof (emphasis added)." The exemplification of **one** data point that is inside a broadly claimed range is not considered to be sufficient evidence to allow an artisan of ordinary skill to determine if there is a **trend** that

supports unexpected results over the entire broad scope claimed. Thus, the results in Figures 2A and 2B are not considered to support a claim for patentability based on unexpected results.

The appellant also argues that "There is no basis for concluding predictability where a composition includes five different constituents, each present in the composition in specific and varying amounts…each of which is mentioned in a different reference…" because it would require limitless numbers of optimizations to arrive that the claimed compositions. However, the cited prior art specifically teaches that each of the claimed ingredients was known in the art at the time of the invention to be useful to treat obesity. The fact that the claimed ingredients might be among numerous other agents suitable for treating obesity does not negate the cited references' explicit teachings suggesting that the claimed ingredients would have been useful for that treatment. The fact that the combination is one of a number of obvious combinations of obesity treatments does not make it any less obvious. Thus, the combination of the prior art is considered to properly teach combining the claimed ingredients together into a single composition.

In addition, in regards to the amounts of each ingredient in the composition, "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The references teach that each of the claimed ingredients is a pharmaceutically active ingredient. An artisan of ordinary skill would routinely modify the amount of pharmaceutically active ingredients based on the patient's age, weight, gender, and condition. The optimization of dosage amount is specifically taught in Liao. This reference suggests effective dosages of EGCG and also suggests varying this dosage based on body weight

and condition of the patient (see paragraph spanning columns 11 and 12). Furthermore, Gow suggests composition which contain 1 to 60% yerba mate extract (see column 20, lines 14-17, 54 and 55). Majeed teaches using 1 to 40% forskohlin extracted from Coleus forskohlii to promote lean body mass (see abstract). These percentages overlap with the percentages claimed by the appellant for these ingredients. Therefore, the amounts of each ingredient as claimed by the appellant are considered to be an obvious modification of the composition suggested by the combination of the references.

The appellant also states that the current claims have been patented in Europe. However, the USPTO is not bound by the findings of any foreign authority. The USPTO must examine patent applications in relation to US statutes and US case law. Following these guidelines has lead to a reasonable conclusion that the claimed invention is not patentable because it is an obvious modification of what was known in the art at the time of the invention.

The appellant further argues that Figure 1 shows that the claimed invention is unobvious because the present combination shows significant inhibition of lipase activity when compared to Xenical without the negative side effects of Xenical. However, to show unexpected results, the claimed invention must be compared with the closest prior art (see MPEP section 716.02(e)). Xenical is a chemical compound that is unrelated to the herbal ingredients currently claimed. Thus, the comparison with Xenical is not considered to show that the claimed invention has any unobvious, unexpected effects. Furthermore, the fact that the claimed composition may not have negative side effects is not considered to support patentability. The fact that the appellant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious.

See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). The references together teach combining the same ingredients as claimed into a single composition. Thus, any advantages in regards to the side effects flows naturally from the suggestion of the prior art to combine the ingredients into a single composition. Therefore, this argument is also not persuasive of error.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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